

Wisconsin Department of Regulation & Licensing

Mail To: P.O. Box 8935
Madison, WI 53708-8935

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Madison, WI 53703
E-Mail: web@drl.state.wi.us
Website: <http://drl.wi.gov>

FOR OFFICE USE

License #: _____
Date Granted: _____
To DOE: _____

MANUFACTURER SELF-INSPECTION REPORT

Application ID Number (if applicable) _____

APPLICANT NAME: _____

DBA NAME: _____

ADDRESS: _____

TELEPHONE: () _____

HOURS: Mon-Fri: _____ Sat _____ Sun _____

PERSONNEL

_____ Change in Ownership

_____ New Location

_____ New Owner

Name of Owner(s): _____

If the facility is in non-compliance with any portions of the “Drug Manufacturer Self-Inspection Report” please indicate why the facility is in non-compliance and when the facility will be in compliance. Return the entire “Drug Manufacturer Self-Inspection Report” to the Board office when completed. Please make a copy for your files.

Chapter Phar 12 Wisconsin Administrative Code (Manufacturer Requirements)

PLACE INITIALS CERTIFYING COMPLIANCE.

Phar 12.03

_____ The establishment is registered with the food and drug administration and complies with all applicable requirements of 21 CFR 200, 201, 202, 207, 210 and 211.

Note-attach copy of the most current food and drug administration inspection.

_____ If applicable, the establishment is registered with the drug enforcement administration and complies with all appropriate requirements of 21 CFR 1301, 1302, 1303, 1304, 1305, 1307, 1311 and 1312.

Note-attach copy of the most current drug enforcement administration inspection.

_____ A manufacturer license may not be transferred from one establishment to another nor from one person to another. Each establishment requires a separate license.

Phar 12.04 1

_____ The establishment meets the current standards of 21 USC 351 and 352 and 21 CFR 210 and 211.

Committed to Equal Opportunity in Employment and Licensing

Wisconsin Department of Regulation & Licensing

AFFIDAVIT

I, the applicant, state that all statements herein contained are each and all strictly true in every respect. I have read the applicable Wisconsin State Statutes and Administrative Code concerning Manufacturer Requirements, am familiar with its provisions, and if granted a license, agree that I will abide by all of said provisions. I understand that false or forged statements made in connection with this application may be grounds for denial or revocation of the Manufacturer's License.

Signature of Applicant

State of _____ County of _____

Subscribed and sworn to before this _____ day of

_____, 20_____, by _____
(Applicant name)

Signature of Notary Public

S E A L

Date Commission Expires

NOTE: This affidavit must be signed by the applicant in the presence of the notary public on the same date.